

SEP - 2 2011

Arthrex SPECIAL 510(k): Arthrex MicroSuture Anchors

2 510(k) Summary of Safety and Effectiveness

<i>Date Summary Prepared</i>	August 2, 2011
<i>Manufacturer/Distributor /Sponsor</i>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<i>510(k) Contact</i>	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: courtney.smith@arthrex.com
<i>Trade Name</i>	MicroSuture Anchors
<i>Common Name</i>	Screw, Fixation, Bone
<i>Product Code - Classification Name</i>	HWC – Screw, fixation, bone MAI – Fastener, fixation, biodegradable, soft tissue MBI – Fastener, fixation, nondegradable, soft tissue 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories. 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
<i>Predicate Devices</i>	<i>K061863</i> : Arthrex Corkscrew Suture Anchor <i>K063479</i> : Arthrex Mini PushLock <i>K091844</i> : Arthrex Micro BioComposite Suture Tak
<i>Device Description and Intended Use</i>	The Arthrex MicroSuture Anchors consist of four anchors which are line extensions to existing anchors. The new anchors are comprised of titanium or PLA/ βTCP and are provided preloaded on a driver with suture. The anchors range from 2.2-2.7mm in diameter and 4-7mm in length. The Arthrex MicroSuture Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below: <i>Elbow:</i> Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction <i>Shoulder:</i> Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction <i>Hand/Wrist:</i> Scapholunate Ligament Reconstruction,

	<p>Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)</p> <p><i>Foot/Ankle:</i> Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction</p> <p><i>Knee:</i> Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis</p>
<p>Substantial Equivalence Summary</p>	<p>The <i>Arthrex MicroSuture Anchors</i> are substantially equivalent to the <i>Arthrex Corkscrew</i>, <i>Arthrex Mini PushLock</i> and <i>Micro BioComposite Suture Tak</i> predicates, in which the basic features, and intended uses are the same. Any differences between the <i>MicroSuture Anchors</i> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The mechanical testing demonstrates that the pull-out strength of the proposed devices meets or exceeds the pull-out strength of the predicate devices. Based on the indication for use, technological characteristics, and the comparison to the predicate device, Arthrex, Inc. has determined that the <i>Arthrex MicroSuture Anchors</i> are substantially equivalent to currently marketed predicate device.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Inc.
% Ms. Courtney Smith
1370 Creekside Blvd.
Naples, Florida 34108-1945

SEP - 2 2011

Re: K112237

Trade/Device Name: Arthrex MicroSuture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MAI, MBI
Dated: August 2, 2011
Received: August 4, 2011

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – Ms. Courtney Smith

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for Mark N. Melkerson

Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number: K112237

Device Name: Arthrex MicroSuture Anchors

Indications For Use:

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The Arthrex MicroSuture Anchors is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Prescription Use ☒ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

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